Remote and eConsents

Medical University of South Carolina

Remote Consent

Also known as “Teleconsent”!

Method of obtaining informed consent using **paper** OR **electronic consent (eConsent)** form where the person obtaining consent and the participant are not in the same physical location during the consent process.

Remote Consent: Paper/Hardcopy

Where a copy of the written informed consent form is provided to the participant via email, fax, mail or during a prior in-person visit.

The informed consent process may be conducted over the phone or via video conference.

The participant signs and dates a hard copy of the consent form and returns it to the study team via email, fax, mail or at their first in-person visit.

Study related procedures may not occur until a signed copy of the consent is in the possession of the study team unless the IRB has approved a waiver of documentation of consent to allow select activities to occur before written consent is finalized.

Electronic Consent (eConsent)

Method of obtaining informed consent through the use of an electronic system instead of a paper consent form (REDCap, DocuSign, etc.).

Electronic Consent: In Person or Remote

eConsent can occur **in person** or **remotely**

- **In person** – Giving a potential participant an iPad that displays the consent form in REDCap, discussing the consent form in person, and then the participant agreeing to participate by tapping the appropriate button in REDCap.
- **Remote** – The study team may give the potential participant a link to the eConsent system and go over the consent information over the phone or via electronic platform. The participant would provide their consent via an electronic platform.

When can I use eConsent?

- Research that qualifies for a waiver of documentation of consent, such as minimal risk research, may use eConsent systems that are not 21 CFR Part 11 compliant.
- If the research is not FDA regulated and posses more than minimal risk, the documentation of legally effective signatures on the consent form is required.
- If the research is FDA regulated (includes drugs or devices) and does not meet the criteria for a waiver of documentation of consent (the study poses more than minimal risk to the participants), the FDA requires that the eConsent system be Part 11 compliant (21 CFR Part 11).

21 CFR Part 11

- When referencing a “Part 11 compliant” electronic consent system, the IRB is referring to use of a system that complies with FDA regulatory requirements for electronic records and electronic signatures.
- Compliance with these regulatory requirements is required for all FDA-regulated research that is greater than minimal risk and minimal risk research where the requirement for documentation of consent has not been waived.
- DocuSign is the only Part 11 compliant system that is currently institutionally approved.
- For FDA-regulated research, REDCap may be used only if the documentation of consent requirement has been waived. A waiver of documentation of consent may only be granted when the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

FDA’s guidance on electronic consent

Common Electronic Consent (E-Consent) Systems			
	DocuSign	Standard REDCap	Modified REDCap*
Is it 21 CFR Part 11 Compliant?	Yes	No	No
Can it be used for greater than minimal risk FDA regulated research? (21 CFR Part 11 compliant required)	Yes	No	No
Can it be used for minimal risk FDA regulated research where documented consent is required?	Yes	No	No
Can it be used for minimal risk FDA regulated research where the IRB has waived documentation of consent?	Yes	Yes	Yes
Can it be used for greater than minimal risk research that is not FDA regulated?	Yes	No	Yes
Can it be used for research that qualifies for waiver of documentation of consent and is not FDA regulated?	Yes	Yes	Yes

*Modified REDCap refers to REDCap that has been modified to include all features necessary to obtain legally effective documented consent.

You must submit your consent plan to the IRB via your eIRB application and IRB approval must be obtained for any consent process or for any change to your consent process to occur.